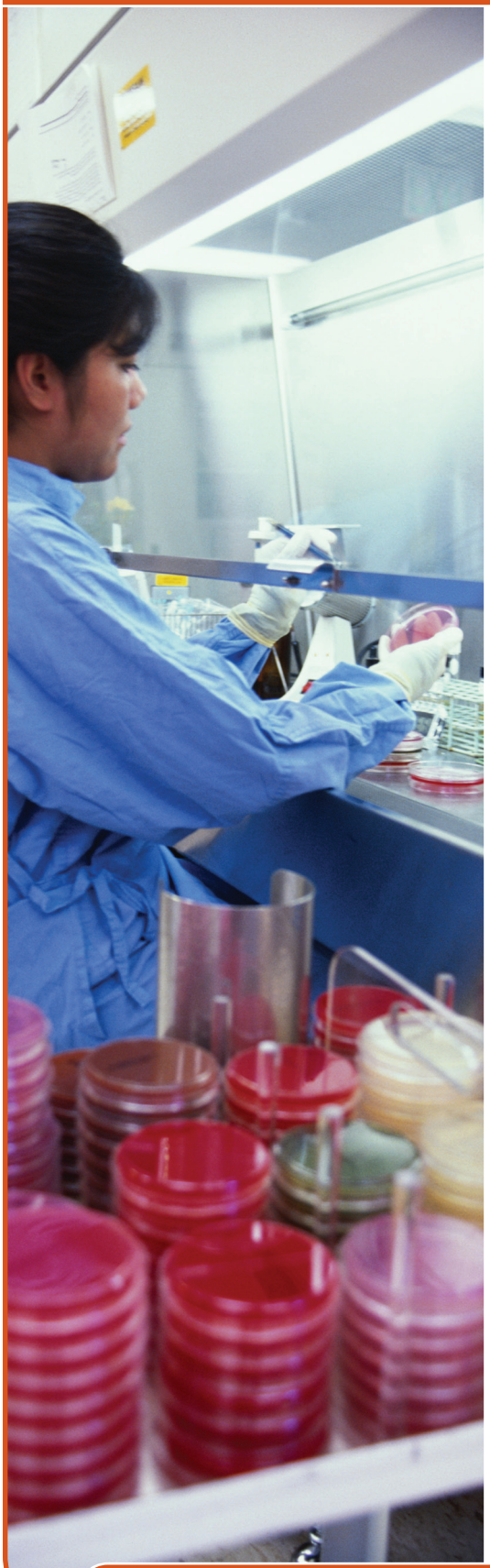
FoodCORE Model Practice: Laboratory Timeliness and Completeness



Introduction:

Laboratory activities are a critical component of enteric disease surveillance and cluster and outbreak detection. Identification of the etiologic agent causing illness requires testing of specimens at local hospitals, clinics, and private laboratories. Laboratory-based surveillance identifies confirmed cases of enteric disease infection and can help guide pathogen-specific response activities. Further characterization of pathogens (e.g. subtype, virulence determinants, antimicrobial susceptibility, etc.) at Public Health Laboratories (PHL) enhances the ability to identify patterns and trends, including clusters of disease that may represent unrecognized outbreaks. Additionally, PHLs also provide primary diagnostic functions in event-associated outbreaks of undetermined etiology.

This FoodCORE Model Practice summarizes the successful laboratory practices used by PHLs in the FoodCORE centers for improving and maintaining the timeliness and completeness of isolate or specimen submissions to the PHL, the subtyping of enteric pathogens, and the communication of laboratory results and cluster detection reports. The activities described would be applicable for surveillance of various pathogens but are focused on those that are likely transmitted via food. A checklist is provided which may be used to determine if current PHL practices align with the FoodCORE model practices.

Appendices:

Appendix A. Checklist for FoodCORE Laboratory Practices

Aligning with other initiatives:

The laboratory model practice document is not intended to replace guidance about laboratory test protocols or participation in reporting to surveillance systems such as the Laboratory-based Enteric Disease Surveillance (LEDS) system, the Nationally Notifiable Disease Surveillance System (NNDSS), PulseNet, and CaliciNet. These FoodCORE laboratory model practices may be used to enhance future guidance documents and protocol development.

National Center for Emerging and Zoonotic Infectious Diseases
Division of Foodborne Waterborne, and Environmental Diseases

CS247978

Receiving specimens:

FoodCORE centers use various practices and systems to help ensure timely and complete submission of specimens from these external sources. These practices include:

- Rapidly transporting isolates/specimens to the PHL for testing to ensure prompt receipt of all requested or required bacterial, viral or parasitic specimens from clinical and commercial laboratories
  - » Rapid transport can be supported with a variety of services such as the provision of mailing containers, a contract courier service, or other means of specimen transport to the PHL
- Providing guidance for submission of patient, food or environmental isolates/ specimens to the PHL when investigating outbreaks of undetermined etiology
- Providing guidance regarding when and how to submit, for further testing at the PHL, Shiga toxin-positive enrichment broths and other primary clinical specimens that are found positive by culture independent diagnostic tests (CIDT) for STEC or other pathogens that meet submission requirements in your jurisdiction

FoodCORE centers also work closely with the clinical and commercial laboratories that submit specimens so any delays or gaps in submissions can be identified. PHLs should reach out to laboratories to encourage submissions and help eliminate barriers to submission if they are identified.

FoodCORE centers also conduct trainings for local health department (LHD) partners. As part of these trainings, submission protocol documents (manuals, standard operating procedure documents, etc.) and shipping materials can be provided to help ensure all partners know the testing capabilities of the PHL, what type of specimens should be collected, as well as when and how to collect and submit them to the PHL.

To help streamline the receipt and testing of specimens, outreach, resources, and trainings for clinical and commercial laboratories and LHD partners, should include guidance stating that the PHL should to be notified when specimens/samples will be submitted for outbreak investigations.

Subtyping and testing specimens:

FoodCORE centers work to improve the timeliness and completeness of subtyping for bacterial, viral, and parasitic specimens submitted to the PHL. Depending on jurisdictional resources, attempts should be made to subtype all primary isolates as soon as they are received at the PHL. Subtyping results should be submitted to the appropriate surveillance network in real-time whenever possible. Additionally, PHLs should follow standard CDC isolate submission policies and respond to requests for submitting isolates for additional testing, such as antimicrobial testing through NARMS, MLVA subtyping, or whole genome sequencing. FoodCORE centers use various practices and systems to help enhance subtyping capacity and timeliness. These practices include:

- Cross-training staff in subtyping protocols; this includes having more than one staff member with a specific certification so there is built-in surge capacity and back-up staffing
- Performing real time subtyping of all strains of *Salmonella*, Shiga toxin-producing *E. coli* (STEC) and *Listeria*. Strategies to achieve this goal include:
  - » Minimizing or eliminating batching so that turnaround times can be improved and then maintained
  - » Initiating subtyping without waiting for pathogen confirmation testing as the proportion of isolates with incorrect primary pathogen identification from diagnostic labs is usually low
  - » Processing *Salmonella* isolates for simultaneous serotyping and PFGE (i.e., in parallel) rather than waiting for serotyping results before initiating PFGE
    - – Not limiting PFGE to specific serotypes because PFGE of all strains, regardless of serotype, increases the sensitivity of cluster detection and eliminates the need to complete serotying before PFGE

» Processing STEC isolates for simultaneous serotyping and PFGE (i.e., in parallel) rather than waiting for serotyping results before initiating PFGE

– When shiga toxin-positive broths are received, they are plated on sorbitol-MacConkey (SMAC) agar. Non-sorbitol fermenting isolates are treated as STEC O157 and sorbitol -fermenting isolates are treated as non-O157 STEC strains for PFGE testing.

– Serotype misclassification based on sorbitol fermenting results is usually low and PFGE can be repeated if necessary after full serotyping is completed.

- Incorporating molecular serotyping when available to reduce turn-around times
- Culture-Independent Diagnostic Testing (CIDT)
  - » Communication with providers/diagnostic laboratories about submission requirements and working together to be sure procedures and samples meet diagnostic and public health needs
    - – Work with APHL and industry initiatives to identify providers and diagnostic laboratories that are implementing CIDT so communications and outreach can be proactive
  - » Identify means for submitting labs to indicate target pathogens based on the CIDT used and the results of their testing to guide PHL processing

Reporting results and cluster detection:

FoodCORE centers capitalize on the completeness and timeliness of specimen subtyping to quickly identify clusters of illness. All subtyping results should be reported to the appropriate surveillance network in real-time whenever possible, based on jurisdictional resources. To enhance reporting and cluster detection, FoodCORE centers use the following practices:

- Routinely analyzing subtyping data from PHL testing to determine if there is an increase in the identification of a specific subtype or strain
- Routinely comparing subtyping results to centralized databases to determine whether there are additional subtype matches
- Using subtyping results to link pathogens identified from product testing to persons infected with the same subtype or strain
- Using shared data systems that permit routine rapid sharing of laboratory information and results for human, food, and environmental isolate testing to inform and facilitate response activities
  - » Real-time sharing of specimen testing and subtyping information during an investigation
- Routinely exchanging cluster detection reports
  - » At a minimum, weekly reporting with more frequent reporting (i.e., twice-weekly, daily, etc.) if possible
  - » Integrated with the routine data analyses to determine if there is an increase in the number of cases of infection with a specific subtype or strain
  - » Additionally, established methods for exchanging information about potential clusters that are detected between scheduled reports should exist
  - » Combined meetings and trainings that include laboratory and epidemiology staff so staff have a working understanding of the needs and capabilities of each group

Appendix A. Checklist for FoodCORE Laboratory Practices

Yes	No	Partial	Will be implemented (Date)	Practice
				Receiving Specimens
				1. Use a courier or equivalent system for rapid transport of specimens/ isolates to the PHL
				2. Provide guidance for the submission specimens under conditions of undetermined etiology
				3. Provide guidance for the submission of clinical specimens that are positive by CIDT for pathogens that meet submission requirements in your jurisdiction
				4. Conduct outreach to clinical or commercial labs with submission delays
				5. Provide guidance materials for PHL testing capabilities/services
				6. Conduct trainings and/or provide reference materials for appropriate specimen collection (type of specimen, how to collect and submit, etc.)
				7. Provide guidance stating that clinical and commercial labs and LHD partners notify the PHL when submitting specimens/samples for outbreak investigations
				Subtyping Specimens
				8. Perform subtyping for all primary isolates received at the PHL in real-time whenever possible
				9. Submit subtyping results to the appropriate surveillance network in real-time whenever possible
				10. Submit isolates to CDC in accordance with standard submission policies and in response to any specific requests
				11. Cross-train staff in subtyping protocols/certifications
				12. Minimize/eliminate batching of isolates for subtyping that would result in longer turnaround times
				13. Initiate subtyping without waiting for pathogen confirmation from diagnostic laboratory testing
				14. Process Salmonella isolates simultaneously for serotyping and PFGE subtyping
				15. Process STEC isolates simultaneously for serotyping and PFGE subtyping
				16. Incorporate molecular serotyping to reduce turnaround times
				17. Provide guidance to providers and diagnostic laboratories about requirements and procedures related to CIDT and submissions to the PHL

Appendix A. Checklist for FoodCORE Laboratory Practices

Yes	No	Partial	Will be implemented (Date)	Practice
				Reporting Results and Cluster Detection
				18. Routinely analyze subtyping results for cluster detection
				19. Routinely compare subtyping results to centralized database results
				20. Link, by subtype, pathogens identified in non-human sources to human illness with the same strain
				21. Use shared data systems that permit rapid sharing of laboratory information across the core areas of response
				22. Exchange subtyping results in real-time during an investigation across the core areas of response
				23. Exchange routine cluster detection results at least weekly and more frequently if possible
				24. Use established methods for exchanging information about potential clusters that are detected between scheduled reports
				25. Participate in combined meetings and trainings that include laboratory and epidemiology staff